Pills, Bills, and Capitol Hill: Reevaluating the Prescription Drug "Rebate Rule" in Light of the Inflation Reduction Act

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ABSTRACT: In 2020, the Department of Health and Human Services promulgated a rule modifying an antikickback safe harbor for Medicare prescription drug rebates. This Note argues that this rule should be reconsidered following the Inflation Reduction Act's advancements in reforming Medicare drug prices. First, this Note discusses the role of rebates in the prescription drug delivery system and explores the development and finalization of the rule. Next, it reviews actuarial studies and financial estimates of the rule's impact on federal Medicare spending and out-of-pocket costs for Medicare Part D beneficiaries. It concludes by suggesting repeal of the rule given that its primary goal—to reduce drug costs for seniors—is already met by the drug pricing provisions in the Inflation Reduction Act.

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INTRODUCTION

Billions of drugs are filled at pharmacies every year in America.[1] When a patient goes to a pharmacy, they often do not realize or appreciate the complexity of the prescription drug delivery system that allows them to fill their prescription. What may seem like a simple enough process—where a pharmacist reviews the prescription, checks if the patient's insurance will cover some or all of the cost of the drug, then dispenses the drug and charges a cost-share amount accordingly—actually involves multiple participants with various incentives and motives. Behind the scenes, pharmacy benefit managers ("PBMs") serve an important role in managing a patient's prescription drug benefits and can greatly impact the price that an individual pays for their necessary drugs.

Although Americans may not fully understand the role that PBMs play in the oversight and control of their prescription drugs, they are likely acutely aware of rising drug prices impacting those with severe drug needs. For example, the average cost of insulin, a critical drug used to control blood sugar levels in diabetes patients,[2] "increased 11 percent annually from 2001

1. *Number of Retail Prescription Drugs Filled at Pharmacies by Payer*, KAISER FAM. FOUND., https://www.kff.org/health-costs/state-indicator/total-retail-rx-drugs/? [https://perma.cc/2J8M-A6YB] (showing that 3,792,051,418 prescriptions were filled at retail pharmacies across the United States in 2019, including 1,058,091,761 prescriptions covered by Medicare).

2. *Diabetes Treatment: Using Insulin to Manage Blood Sugar*, MAYO CLINIC (Aug. 7, 2021), https://www.mayoclinic.org/diseases-conditions/diabetes/in-depth/diabetes-treatment/art-20044084 [https://perma.cc/6DXS-2SD3].

to 2018."[3] This drastic increase in price affects millions of Americans with diabetes, including twenty-five percent of adults over age sixty-five—the Medicare-eligible population.[4]

Current PBM practices impact a significant number of Americans. In 2021, over sixty-three million Americans were covered by Medicare,[5] encompassing nearly twenty percent of the U.S. population.[6] Over three-quarters of these Medicare members also chose to enroll in optional Part D benefits, opting into coverage packages referred to as "drug plans," to help cover the cost of prescription drugs.[7] The drug plan, however, does not cover the entire cost of prescription drugs. For example, the average cost for a Medicare Part D member to fill an insulin prescription in 2017 was $57.[8] That same prescription would have cost the member $39 to fill just ten years earlier.[9]

Depending on the specific brand of insulin that a Medicare member uses, the work of a PBM can greatly affect their overall drug costs. This price variability occurs because the tier placement of the drug, which PBMs negotiate on behalf of drug plans, impacts the cost-sharing levels that the patient ultimately pays for the drug.[10] Additionally, PBMs negotiate the list prices of drugs, which in turn affect the out-of-pocket costs—namely the coinsurance percentages applied to each sale—paid by Medicare members.[11] Because of the relationship between a drug's list price and member out-of-pocket costs,

3. Tara O'Neill Hayes & Josee Farmer, *Insulin Cost and Pricing Trends*, AM. ACTION F. (Apr. 2, 2020), https://www.americanactionforum.org/research/insulin-cost-and-pricing-trends [https://perma.cc/9JXF-JXD8].

4. Linda J. Andes et al., *Diabetes Prevalence and Incidence Among Medicare Beneficiaries—United States, 2001–2015*, 68 MORBIDITY & MORTALITY WKLY. REP. 961, 961 (2019).

5. *CMS Releases Latest Enrollment Figures for Medicare, Medicaid, and Children's Health Insurance Program (CHIP)*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Dec. 21, 2021), https://www.cms.gov/newsroom/news-alert/cms-releases-latest-enrollment-figures-medicare-medicaid-and-childrens-health-insurance-program-chip [https://perma.cc/K55W-S4HC].

6. Preeti Vankar, *Medicare - Statistics & Facts*, STATISTA (Feb. 22, 2023), https://www.statista.com/topics/1167/medicare/#topicOverview [https://perma.cc/G87Z-Z7F5].

7. OFF. OF ENTER. DATA & ANALYTICS, CTRS. FOR MEDICARE & MEDICAID SERVS., CMS FAST FACTS 1 (2022), https://data.cms.gov/sites/default/files/2022-08/4f0176a6-d634-47c1-8447-b074f014079a/CMSFastFactsAug2022.pdf [https://perma.cc/Z2AV-7SB8] (showing that of the 63.9 million Medicare members in 2021, 48.8 million also enrolled in Part D benefits).

8. Juliette Cubanski, Tricia Neuman, Sarah True & Anthony Damico, *Insulin Costs and Coverage in Medicare Part D*, KAISER FAM. FOUND. (June 4, 2020), https://www.kff.org/medicare/issue-brief/insulin-costs-and-coverage-in-medicare-part-d [https://perma.cc/NF4W-W5SH].

9. *Id.*

10. *See id.* (showing variations in median total out-of-pocket costs, coinsurance percentages, and copayment amounts for various insulin products by specific drug type and tier placement); *see also infra* notes 28–30 and accompanying text (describing the relationship between tier levels and price within drug formularies).

11. *See* Sara Hansard, *The Driver Dictating Prescription Drug Benefits: PBMs Explained*, BL (Mar. 3, 2022, 5:45 AM), https://news.bloomberglaw.com/health-law-and-business/the-driver-dictating-prescription-drug-benefits-pbms-explained [https://perma.cc/45B5-HD2F].

member expenses increase when the total price of the drug rises, even if the member has Part D drug coverage.[12]

Recently, lawmakers have sought to address the rising costs of prescription drugs through reform efforts and increased regulation in the pharmaceutical industry.[13] PBMs became a target of reform due to their large role in the drug pricing and delivery system.[14] This Note explores one recent reform effort undertaken by the Department of Health and Human Services ("HHS") related to PBMs. The "Rebate Rule" was introduced to combat rising drug prices by preventing PBMs from offering rebates to prescription drug plans.[15] However, studies have drawn viable conclusions suggesting that the rule may actually increase Medicare spending and premiums.[16]

This Note argues that the Inflation Reduction Act's ("IRA") statutory cap on out-of-pocket drug expenses nullifies the necessity of the Rebate Rule. Given that credible studies have concluded that the Rebate Rule may actually increase federal Medicare spending and beneficiary premiums, repeal of the rule is necessary to balance the competing interests between individual beneficiary spending and overall federal spending on Medicare.

First, this Note describes PBMs generally, then explores the common practice of PBMs and drug manufacturers to negotiate rebates as part of the drug pricing scheme. It continues by outlining the history and impact of the HHS regulation finalized in 2020 to prevent the use of rebates by PBMs. The Note then identifies the negative estimated impact that the rule will have on federal spending and Medicare member out-of-pocket costs. Finally, this Note evaluates the impact of the rule in light of other reform efforts included in the IRA and suggests repeal of the rule to prevent estimated premium increases for Medicare Part D members.

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12. Hayes & Farmer, *supra* note 3 ("Patients' prescription out-of-pocket (OOP) costs—increasingly calculated as a percentage of the cost (co-insurance), rather than a fixed dollar amount (co-payment)—are typically based on a medicine's list price, rather than the net price. As list prices rise, so do patients' OOP costs.").

13. *See, e.g.*, Bobby Clark & Marlene Sneha Puthiyath, *Are Pharmacy Benefit Managers the Next Target for Prescription Drug Reform?*, COMMONWEALTH FUND (Apr. 20, 2022), https://www.commonwealthfund.org/blog/2022/are-pharmacy-benefit-managers-next-target-prescription-drug-reform [https://perma.cc/7QTY-4FY5] ("[Lawmakers] have advanced policy proposals to empower the Secretary of Health and Human Services to negotiate prices for certain drugs, require drugmakers to provide rebates when the price of medicines exceeds inflation, and redesign the Medicare prescription drug benefit to include an out-of-pocket spending cap for beneficiaries.").

14. *Id.*

15. Rebate Rule, 85 Fed. Reg. 76666, 76666 (Nov. 30, 2020) (to be codified at 42 C.F.R. pt. 1001).

16. *See infra* notes 139–49 and accompanying text.

I. THE ROLE OF PHARMACY BENEFIT MANAGERS AND PRESCRIPTION DRUG REBATES

The controversial nature of the prescription drug rebate system reflects the complexity of prescription drug coverage and pricing in America today. To describe the function and use of rebates in the Medicare Part D context, Section A first describes the role of prescription drug plans in Medicare coverage. Section B then outlines the relationship between PBMs, drug manufacturers, and prescription drug plans. Next, Section C explains the legal framework that allows rebates to fit within the drug pricing system and describes recent efforts to reform the rebate scheme. Finally, Section D explores the history and future of the "Rebate Rule" introduced by the Trump Administration to eliminate the ability of drug manufacturers to offer rebates to PBMs that administer Medicare Part D plans.

A. THE RISE OF MEDICARE PART D COVERAGE

Medicare Part D prescription drug plans serve an important role in covering the cost of prescription drugs for Medicare beneficiaries. Traditional Medicare coverage includes Part A coverage for hospital, nursing home, and home health services, and Part B coverage for physicians' services and a variety of other items and services.[17] "At the time Medicare was created in 1965, . . . [p]rescription drugs were still relatively affordable and were not as important a part of the management of medical problems as they are today."[18] As a result, outpatient prescription drugs were not originally included in traditional Medicare coverage.[19] In 2003, the Medicare Modernization Act overhauled Medicare to address changes in the health delivery system.[20] The Act introduced Medicare Part D as an optional pharmaceutical benefit that covers prescription drugs.[21]

Unlike traditional Medicare, which can be administered directly by the government, the Medicare Part D program is administered exclusively by private insurers who offer prescription drug plans.[22] All individuals eligible

17. *Parts of Medicare*, MEDICARE.GOV, https://www.medicare.gov/basics/get-started-with-medicare/medicare-basics/parts-of-medicare [https://perma.cc/Y3TU-N796].

18. BRIETTA R. CLARK, ERIN C. FUSE BROWN, ROBERT GATTER, ELIZABETH Y. MCCUSKEY & ELIZABETH PENDO, HEALTH LAW: CASES, MATERIALS AND PROBLEMS 604 (9th ed. 2022).

19. *See History: CMS' Program History*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Dec. 1, 2021, 7:02 PM), https://www.cms.gov/About-CMS/Agency-Information/History [https://perma.cc/CKN5-UXRX].

20. *See generally* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (introducing provisions to modernize the Medicare system and expand its coverage).

21. *See generally id.* § 101 (establishing prescription drug coverage).

22. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEPT. OF HEALTH & HUM. SERVS., HOW MEDICARE PRESCRIPTION DRUG COVERAGE WORKS WITH A MEDICARE ADVANTAGE PLAN OR MEDICARE COST PLAN 1 (2018), https://www.medicare.gov/Pubs/pdf/11135-prescription-drug-coverage-with-ma-mcp.pdf [https://perma.cc/F97C-V8S2].

for Medicare can opt into Part D coverage and "enroll in either a stand-alone prescription drug plan . . . to supplement traditional Medicare" or add Part D drug coverage to a Medicare Advantage managed care plan.[23] In 2022, forty-nine million individuals opted into Part D coverage, representing over seventy-five percent of Medicare beneficiaries.[24] This Part D population has more than doubled since 2006, the first year the benefit became available to Medicare members.[25]

B. THE INTERPLAY BETWEEN PHARMACY BENEFIT MANAGERS, DRUG MANUFACTURERS, AND PRESCRIPTION DRUG PLANS

Although the intricacies of PBMs are unknown to most patients when they fill prescriptions, PBMs serve a significant role in the delivery of prescription drugs. PBMs negotiate with all entities except patients in the prescription drug distribution chain.[26] The complex system of prescription drug pricing and delivery begins with the companies that manufacture the drugs. Drug manufacturers set prices for drugs, called list prices, which determine how much a patient pays when they fill a prescription at the pharmacy. When the patient has insurance, they pay a portion of the list price to the pharmacy in the form of a copay, with the rest of the cost covered by their insurance provider through their prescription drug plan coverage.[27] Behind the scenes, however, PBMs serve as middlemen between drug manufacturers and health insurance companies. PBMs simultaneously work on behalf of health insurers to develop the insurers' formularies for their prescription drug plans and with drug manufacturers to negotiate prices for

23. *An Overview of the Medicare Part D Prescription Drug Benefit*, KAISER FAM. FOUND. (Oct. 19, 2022), https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit [https://perma.cc/XX2X-G8DR].

24. *Id.*

25. In 2006, twenty-two million members elected to enroll in Part D coverage—just over half of the forty-three million Medicare beneficiaries that year. Juliette Cubanski & Anthony Damico, *Key Facts About Medicare Part D Enrollment, Premiums, and Cost Sharing in 2021*, KAISER FAM. FOUND. (June 8, 2021), https://www.kff.org/medicare/issue-brief/key-facts-about-medicare-part-d-enrollment-premiums-and-cost-sharing-in-2021 [https://perma.cc/NH56-X59U] (showing twenty-two million Part D enrollees in 2006); U.S. CENSUS BUREAU, MEDICARE ENROLLMENT - NATIONAL TRENDS 1966-2013, https://www.census.gov/history/pdf/medicare1966-2013.pdf [https://perma.cc/SG3K-DSUH] (showing forty-three million total Medicare enrollees in 2006).

26. *See* ANNA COOK, THOMAS KORNFIELD & MARSHA GOLD, THE ROLE OF PBMS IN MANAGING DRUG COSTS: IMPLICATIONS FOR A MEDICARE DRUG BENEFIT 7 (2000), https://www.kff.org/wp-content/uploads/2013/01/the-role-of-pbms-in-managing-drug-costs-implications-for-a-medicare-drug-benefit.pdf [https://perma.cc/LZ6Z-5FER] ("PBMs are companies that process pharmaceutical claims on behalf of health plans, HMOs, and employers while managing drug utilization and obtaining discounts from both retail pharmacies and manufacturers.").

27. *See* Joanna Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, 38 YALE L. & POL'Y REV. 360, 362 (2020) ("[P]atients with insurance typically have cost-sharing obligations that require them to pay between thirty and forty percent of list prices.").

drugs covered on the drug plan's formulary.[28] In this way, PBMs act as third-party brokers to facilitate negotiations between the drug manufacturer and the drug plan.

Both manufacturers and health insurers benefit from their relationship with PBMs. Manufacturers offer rebates to PBMs in exchange for preferred placement on the drug plan's formulary.[29] By negotiating with PBMs, drug manufacturers can ensure their drugs are placed on a lower tier of a plan's formulary, thereby encouraging plan members to use these drugs, since drugs that are on lower tiers typically have lower copays.[30] Once a PBM negotiates the formulary and the drug plan approves it, the patient enters the drug delivery system.

Although patients do not directly interact with PBMs, the rebate system impacts the price of their prescription drugs. When a patient fills a prescription for a given drug, the drug's manufacturer pays a negotiated percentage of the drug's list price to the PBM in the form of a rebate.[31] PBMs often pass some of these savings to the patient's insurance company,[32] which may incorporate estimated rebate amounts into premium calculations that it charges members.[33] Although rebates may indirectly flow to the member through reduced premiums, they do not directly lower the out-of-pocket cost that members pay for the drug. Even if the drug manufacturer offers rebates on their drugs, the cost the member pays for the drug at the pharmacy is based on the drug's list price, not the postrebate price.[34]

PBMs hold significant control within the drug pricing system, which can lead to conflicts of interest related to the use and potential abuse of rebates. The drug pricing business model provides PBMs with powerful leverage, though "the inherent competitive nature of formularies makes them susceptible to manipulation by drug manufacturer pricing practices."[35] Even so, because

28. *Id.* at 364–68. A formulary is the list of generic and brand-name prescription drugs covered by a specific plan. *What Is a Tiered Formulary and What Does It Mean for Me?*, UNITED HEALTHCARE, https://www.uhc.com/news-articles/medicare-articles/what-is-a-tiered-formulary-and-what-does-it-mean-for-me [https://perma.cc/5DLA-5727]. A drug's tier placement on the formulary impacts its price. *See id.*

29. Shepherd, *supra* note 27, at 361.

30. *See What Is a Tiered Formulary and What Does It Mean for Me?*, *supra* note 28.

31. Shepherd, *supra* note 27, at 366–67.

32. *Pharmacy Benefit Managers and Their Role in Drug Spending*, COMMONWEALTH FUND (Apr. 22, 2019), https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending [https://perma.cc/DSW9-LACF] ("A recent study found that the share of rebates PBMs passed through to insurers and payers increased from 78 percent in 2012 to 91 percent in 2016.").

33. *See* Shepherd, *supra* note 27, at 370.

34. *See* Joey Mattingly, *Understanding Drug Pricing*, U.S. PHARMACIST (June 20, 2012), https://www.uspharmacist.com/article/understanding-drug-pricing [https://perma.cc/A99P-BEBY].

35. Abigail Gore, Comment, *Exposing the Middlemen in Rising Drug Costs: Modifying Safe Harbor Protections for Pharmacy Benefit Manager Rebates Under Federal Anti-Kickback Statutes*, 98 OR. L. REV. 297, 302 (2020).

the rebates paid to PBMs are calculated based on a percentage of the list price of the drug, PBMs have an incentive to negotiate for drugs that are more expensive.[36] When the drugs that PBMs negotiate to include on drug plan formularies have higher list prices, the potential rebate payments the PBMs receive are also higher. Because of this, PBMs may be incentivized to negotiate formularies not based on what is best for members, but rather with their own financial interests in mind. This cyclical incentive structure further encourages PBMs to pressure drug manufacturers to raise list prices on all drugs, leading to increased rebate payments to improve their own profits.[37]

C. THE LEGALITY OF REBATES IN PRESCRIPTION DRUG PRICING AND EFFORTS TO REFORM THE REBATE SYSTEM

Under federal law, a regulatory safe harbor allows PBMs to receive prescription drug rebates without antikickback liability.[38] Federal fraud and abuse law prohibits "remuneration (including any kickback, bribe, or rebate) . . . in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program."[39] This law effectively prohibits participants in the health care delivery system from benefitting from kickbacks that encompass any transfer of value.[40] The antikickback statute protects patients' healthcare decision-making power and reduces unnecessary or expensive medical costs by prohibiting financial rewards given to induce referrals or incentivize the purchase of goods, items, or services paid for by a federal health program, including Medicare.[41]

Although the PBM rebate scheme on its face would be considered an illegal remuneration under the antikickback statute, a safe harbor protection promulgated by HHS allows drug manufacturers and PBMs to utilize rebates without facing antikickback penalties.[42] This regulatory safe harbor protects discounts that act as "a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction" on items that are purchased by federal health care programs—effectively describing the activities of the rebate scheme, which offers reductions in drug list prices for a PBM acting as a group purchasing organization.[43] The safe harbor carves

36. Shepherd, *supra* note 27, at 377.
37. *Id.* at 378.
38. *See* 42 C.F.R. § 1001.952(h)(5) (2021).
39. 42 U.S.C. § 1320a-7b(b)(1)(A) (2018).
40. Gore, *supra* note 35, at 306.
41. *See* CLARK ET AL., *supra* note 18, at 889.
42. 42 C.F.R. § 1001.952(h)(5).
43. *Id.*

out the rebate-related activity of PBMs from antikickback liability to "encourag[e] price competition that benefits the Medicare and Medicaid programs."[44]

The use of rebates impacts competition in the drug manufacturing space by "offer[ing] pharmaceutical manufacturers the prospect of substantially increased sales opportunities."[45] Drug manufacturers can offer rebates to PBMs in exchange for their drug's placement on a lower tier of a drug plans' formulary.[46] Preferred placement on the drug plan's formulary allows manufacturers to gain a larger market share of prescription drug users because the out-of-pocket costs to the member will be lower to obtain that drug compared to similar drug options.[47]

Additionally, PBMs hold power over drug manufacturers due to their control and influence over the manufacturers' potential inclusion in a drug plan's formulary. As the Federal Trade Commission explains, "[w]henever PBMs have a credible threat to exclude pharmaceutical manufacturers from their formulary, manufacturers have a powerful incentive to [negotiate] aggressively."[48] The PBM's position in the drug delivery system thus encourages drug manufacturers to negotiate for lower prices to compete with other manufacturers for inclusion and favorable placement on a drug plan formulary.[49] Since 1999, this antikickback safe harbor has ensured the continued existence of the rebate scheme and cemented the pivotal role of PBMs within the drug pricing system.

However, due to the perverse incentive structure that arises from PBMs' unique position in the prescription drug distribution chain,[50] PBMs have recently emerged as a target of reform to reduce drug prices for American consumers.[51] Recent reform efforts to modify the rebate scheme in the drug distribution chain have typically been premised on the general proposal to

44. Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088, 3092 (proposed Jan. 23, 1989) (to be codified at 42 C.F.R. pt. 1001).

45. Letter from Susan A. Creighton, Dir., Bureau of Competition, Fed. Trade Comm'n, Luke M. Froeb, Dir., Bureau of Econ., Fed. Trade Comm'n, Maureen K. Ohlhausen, Acting Dir., Off. of Pol'y Plan., Fed. Trade Comm'n & David A. Hyman, Special Couns., Fed. Trade Comm'n, to Greg Aghazarian, Assembly Member, Cal. State Assembly 9 (Sept. 7, 2004), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v040027.pdf [https://perma.cc/N6FX-542Q].

46. *See supra* notes 29–30 and accompanying text.

47. *See* Letter from Susan A. Creighton et al., to Greg Aghazarian, *supra* note 45, at 6.

48. *Id.* at 9.

49. *See id.* at 6.

50. *See supra* Section I.B.

51. *See, e.g.*, Michael A. Carrier, *A Six-Step Solution to the PBM Problem*, HEALTH AFFS.: HEALTH AFFS. FOREFRONT (Aug. 30, 2018), https://www.healthaffairs.org/do/10.1377/forefront.20180823.383881/full [https://perma.cc/89SJ-FVPX].

eliminate rebates paid to PBMs altogether.[52] Rebate elimination discussions are often paired with proposals to pass the eliminated rebate amount to consumers through premiums or at the point of sale at the pharmacy.[53] Other proposals "allow the practice to continue but suggest reforms to ensure that rebates do not increase list prices or impose other harms on drug plans and consumers."[54] By "decoupling the rebate amount from the list price," supporters argue that reform efforts like these would ensure the incentive structure of the rebate system does not encourage manufacturers and PBMs to arbitrarily increase list prices to raise their own profits.[55]

Many economists and analysts, however, believe that eliminating PBM rebates would actually increase the total cost of drugs.[56] Despite conflicting views and inconsistent financial estimates surrounding the impact of rebates on drug prices, recent rulemaking by HHS has aimed to eliminate the safe harbor protection for PBM rebates and create a new safe harbor to pass the value of these rebates to consumers at the pharmacy.[57]

D. HISTORY AND DEVELOPMENT OF THE "REBATE RULE"

In 2020, the Trump Administration finalized a regulatory rule, known as the "Rebate Rule," that amended the federal antikickback statute.[58] The Rebate Rule eliminated the safe harbor protection for PBM rebates in Medicare plans by "classify[ing] payments from drug manufacturers to PBMs as 'kickbacks,' making them illegal under the new [regulation]."[59] The rule also introduced a new regulatory safe harbor protection for discounts that are passed to members when they buy drugs at pharmacies.[60] By preventing PBMs and drug manufacturers from benefitting from rebates, the rule aimed to

52. *See, e.g.*, Kelly Brantley, Lance Grady, Megan West (Olsen) & Tiernan Meyer, *Eliminating Drug Rebates Requires Complex Solutions*, AVALERE (Aug. 16, 2018), https://avalere.com/insights/eliminating-drug-rebates-requires-complex-solutions [https://perma.cc/8JWB-S5CB].

53. Shepherd, *supra* note 27, at 392–95 (advocating for a move to a point-of-sale rebate system). *See generally* Charles C. Yang, *Prescription Drug Insurance Plans: Potential Cost Reductions and the Pass-Through of Manufacturer Pharmaceutical Rebates to Premiums*, 38 J. INS. REGUL., no. 9, 2019, at 1 (analyzing the impact of pharmaceutical rebates as applied to premium amounts).

54. Shepherd, *supra* note 27, at 388.

55. *Id.* at 391.

56. *See, e.g.*, Eric V. Schlecht, *Eliminating Rebates in Medicare Part D Will Not Reduce Drug Prices*, REGUL., Fall 2020, at 8, 8 ("Eliminating rebates only raises premiums, which is something that the Congressional Budget Office has recognized and the Centers for Medicare & Medicaid Services' actuarial analysis of the proposed order has acknowledged."); *see also infra* notes 139–49 and accompanying text (reviewing actuarial studies analyzing the financial impact of the Rebate Rule).

57. Rebate Rule, 85 Fed. Reg. 76666 (Nov. 30, 2020) (to be codified at 42 C.F.R. pt. 1001).

58. *Id.*

59. Stacie B. Dusetzina & Peter B. Bach, *Prescription Drugs—List Price, Net Price, and the Rebate Caught in the Middle*, JAMA NETWORK (Mar. 6, 2019), https://jamanetwork-com.proxy.lib.uiowa.edu/journals/jama/fullarticle/2727874 [https://perma.cc/Z9L9-F7MQ].

60. *See* Rebate Rule, 85 Fed. Reg. at 76717.

reduce incentives for manufacturers to increase drug prices.[61] HHS introduced these changes to pass rebate savings to Part D members directly at the point of sale, rather than allowing PBMs and plans to profit from the rebate system.[62] The promulgation of the rule drew both criticism and support from various pharmaceutical organizations, the general public, and legislators. To understand the impact of the Rebate Rule, it is important first to review the development of the rule and the subsequent challenges and delays to its implementation.

1. Initial Proposal and Finalization of Rule

In recent years, the cost of health care has been an increasing concern for both the federal government and American citizens. Voters have considered the cost of health care and rising drug prices to be significant issues in recent presidential elections.[63] Plans to reduce health care costs were featured heavily in President Trump's 2016 campaign platform.[64] Once President Trump assumed office, his administration continued to pledge to address drug prices.[65] In May 2018, HHS and the Trump Administration released their drug pricing strategy blueprint and proposed "[m]easures to restrict the use of rebates, including revisiting the safe harbor under the Anti-Kickback statute for drug rebates."[66]

In response to the Trump Administration's proposal to reform the rebate system in Medicare Part D plans, various health and pharmaceutical agencies and advocacy groups submitted comments to HHS analyzing and critiquing

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61. U.S. DEP'T OF HEALTH & HUM. SERVS., FACT SHEET: TRUMP ADMINISTRATION PROPOSES TO LOWER DRUG COSTS BY TARGETING BACKDOOR REBATES AND ENCOURAGING DIRECT DISCOUNTS TO PATIENTS 1–2, https://www.hhs.gov/sites/default/files/20190131-fact-sheet.pdf [https://perma.cc/5X4S-CPBR].

62. *See id.* at 3.

63. *See* Ashley Kirzinger, Bryan Wu & Mollyann Brodie, *Kaiser Health Tracking Poll: September 2016*, KAISER FAM. FOUND. (Sept. 29, 2016), https://www.kff.org/report-section/kaiser-health-tracking-poll-september-2016-politics-and-rx-costs [https://perma.cc/Z36W-VGGP]; Ashley Kirzinger, Audrey Kearney & Mollyann Brodie, *KFF Health Tracking Poll—February 2020: Health Care in the 2020 Election*, KAISER FAM. FOUND. (Feb. 21, 2020), https://www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-february-2020 [https://perma.cc/85RJ-EBMA].

64. *See, e.g.*, Jeremy Diamond, *Donald Trump Releases Health Care Reform Plan*, CNN (Mar. 3, 2016, 3:18 PM), https://www.cnn.com/2016/03/02/politics/donald-trump-health-care-plan/index.html [https://perma.cc/G8PY-TRHZ].

65. *See, e.g.*, Julie Rovner, *Trump Highlights Health Agenda with Vow to Lower 'Unfair' Drug Prices*, NBC NEWS (Feb. 6, 2019, 10:03 AM), https://www.nbcnews.com/health/health-news/trump-highlights-health-agenda-vow-lower-unfair-drug-prices-n968281 [https://perma.cc/LYG4-GFHW]; Paige Minemyer, *Trump Unveils 'American Patients First' Plan to Bring Down Drug Costs*, FIERCE HEALTHCARE (May 11, 2018, 2:41 PM), https://www.fiercehealthcare.com/regulatory/trump-unveils-american-patients-first-plan-to-bring-down-drug-costs [https://perma.cc/ZW22-ZMEN].

66. U.S. DEP'T OF HEALTH & HUM. SERVS., AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS 11 (2018), https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf [https://perma.cc/3TNW-BUDH].

the impact of the proposed changes under the rule.[67] Although the pharmaceutical industry generally supported reform to improve the prescription drug system and address increases in drug prices, its lobbyists opposed solutions that would increase costs for members and cautioned HHS that "the discount safe harbor is limited as a tool to address the misaligned incentives in the drug channel."[68] Critics also "argued that [the proposal] target[ed] the wrong piece of the pharmaceutical supply chain," suggesting that reform efforts would be more effective through restraints on drug manufacturers that "put pressure on drug companies to lower their prices."[69]

Despite estimates that the proposal would increase federal Medicare spending, members' out-of-pocket costs, and Part D premiums, HHS officially released its proposed Rebate Rule in February 2019.[70] Following the release, HHS and the Trump Administration received significant pushback from PBMs concerned about the financial impacts of the rule.[71] White House officials believed that its cost was excessive and that the rule may have unintended consequences for other congressional efforts to lower drug costs due to its impact on Medicare Part D premiums.[72] After "careful analysis and thorough consideration," HHS withdrew the proposed rule in July 2019,[73] just five months after its initial release.

In "a sharp reversal" one year later, the Trump Administration weighed a potential reinstatement of the rule after several White House officials who

67. *See, e.g.*, BLAKE PELZER & PAUL SPITALNIC, OFF. OF THE ACTUARY, CTRS. FOR MEDICARE & MEDICAID SERVS., PROPOSED SAFE HARBOR REGULATION 8–9 (2018), https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf [https://perma.cc/VMR2-C6TV]; PHARM. RSCH. & MFRS. OF AM., COMMENTS OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA 13–24 (2018), https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-RFI-Comments-on-HHS-Blueprint-to-Lower-Drug-Prices-and-Reduce-Out-of-Pocket-Costs5.pdf [https://perma.cc/UVA2-7AAE].

68. PHARM. RSCH. & MFRS. OF AM., *supra* note 67, at 4–5, 23.

69. Paige Minemyer, *CBO: HHS' Rebate Rule Would Boost Federal Spending by $177B, Lead to Higher Part D Premiums*, FIERCE HEALTHCARE (May 2, 2019, 4:29 PM), https://www.fiercehealthcare.com/payer/cbo-hhs-rebate-rule-would-boost-federal-spending-by-177b-lead-to-higher-part-d-premiums [https://perma.cc/4HWG-MU63].

70. Proposed Rebate Rule, 84 Fed. Reg. 2340, 2340 (proposed Feb. 6, 2019) (to be codified at 42 C.F.R. pt. 1001).

71. *See, e.g.*, Press Release, Pharma. Care Mgmt. Ass'n, New Analysis: HHS Proposed Rebate Rule 'Poorly Conceived' (Apr. 4, 2019), https://www.pcmanet.org/new-analysis-hhs-proposed-rebate-rule-poorly-conceived [https://perma.cc/GE8W-LQFX].

72. *See* Yasmeen Abutaleb, Amy Goldstein & Ashley Parker, *Trump Kills Key Drug Price Proposal He Once Embraced*, WASH. POST (July 11, 2019, 10:12 AM), https://www.washingtonpost.com/business/economy/white-house-kills-key-drug-pricing-rule-to-eliminate-hidden-rebates/2019/07/11/ff595192-a3de-11e9-bd56-eac6bb02d01d_story.html [https://perma.cc/WR4V-7YR2].

73. Angelica LaVito, *White House Drops Proposal to Eliminate Drug Rebates. Health Stocks Soar*, CNBC (July 11, 2019, 8:06 AM), https://www.cnbc.com/2019/07/11/white-house-pulls-proposal-to-eliminate-drug-rebates-politico.html [https://perma.cc/M8SU-V83U].

opposed the rule in 2019 left their positions.[74] The rule gained fresh momentum by new staffers, including Chief of Staff Mark Meadows, who wanted to deliver policy wins for President Trump ahead of his re-election campaign.[75] In July 2020, President Trump issued an executive order resurrecting the Rebate Rule and directed the Secretary of HHS, Alex Azar, to "complete the rulemaking process."[76] Along with this instruction, the Order directed the Secretary to confirm that the rule would not increase federal spending, member premiums, or out-of-pocket costs, as previous actuarial projections indicated.[77]

HHS finalized the rule in November 2020, making no significant structural changes from the original rule proposed in February 2019.[78] Although Secretary Azar did confirm that the rule would not increase federal spending and member costs, he did not state a basis for this evaluation of the rule's financial impact.[79] As HHS acknowledged in the rule itself, "[t]he full magnitude of [the estimated savings as a result of the rule] is difficult to quantify."[80] The perceived unpredictability of the rule's financial impacts can likely be attributed "to the complexity and uncertainty of stakeholder response,"[81] though actuarial studies have demonstrated that the rule may actually increase Medicare spending and premiums.[82] Indeed, concerns about the cost of the rule and the impact that it would have on federal spending led to the initial withdrawal of the rule when it was first proposed[83] as well as calls for a delay or repeal of the rule by advocacy groups once it was finalized.[84]

2. Implementation Delays and Inclusion in the Inflation Reduction Act

When HHS finalized the Rebate Rule in November 2020, its amendments to the federal antikickback law were scheduled to take effect on January 1, 2022.[85] Shortly after HHS finalized the rule, the Pharmaceutical

74. Adam Cancryn & Sarah Owermohle, *White House Weighs Resurrecting Key Drug Price Initiatives*, POLITICO (July 20, 2020, 7:07 PM), https://www.politico.com/news/2020/07/20/white-house-drug-rebates-374240 [https://perma.cc/UR94-PC4E].

75. *See id.*

76. Exec. Order No. 13,939, 85 Fed. Reg. 45,759 (July 24, 2020); Cancryn & Owermohle, *supra* note 74.

77. *Id.*

78. Rachel Sachs, *Administration Finalizes Drug Pricing Rebate Rule at the Last Minute*, HEALTH AFFS.: HEALTH AFFS. FOREFRONT (Nov. 23, 2020), https://www.healthaffairs.org/do/10.1377/forefront.20201122.985836/full [https://perma.cc/Q8PA-XHMX].

79. *Id.*

80. Rebate Rule, 85 Fed. Reg. 76666, 76719 (Nov. 30, 2020) (to be codified at 42 C.F.R. pt. 1001).

81. *Id.* at 76723.

82. *See infra* Section II.B.

83. Abutaleb et al., *supra* note 72.

84. Robert King, *Insurers, PBMs Call on Congress to Get Rid of Delayed Part D Rebate Rule*, FIERCE HEALTHCARE (Mar. 17, 2021, 3:10 PM), https://www.fiercehealthcare.com/payer/insurers-pbms-call-congress-to-get-rid-delayed-part-d-rebate-rule [https://perma.cc/WW3Z-DKXH].

85. Rebate Rule, 85 Fed. Reg. at 76666.

Care Management Association ("PCMA") initiated a lawsuit against HHS challenging the Rebate Rule.[86] PCMA asked the U.S. District Court for the District of Columbia to vacate the rule, arguing that the promulgation of the rule "exceed[ed] [HHS]'s statutory authority, violate[d] the [Administrative Procedure Act]'s notice-and-comment-rulemaking requirement, and depart[ed] from settled principles of agency rulemaking."[87] PCMA also argued that the rule was arbitrary and capricious due to its disruptive effect on the bidding process for the upcoming year,[88] and that the rule would result in increased federal spending and higher premiums for beneficiaries.[89] Citing actuarial studies performed by Wakely and HHS, PCMA argued that "[f]or most Medicare Part D enrollees, the Rule will not achieve its objective of lowering out-of-pocket spending and will only harm them with higher premiums."[90] On January 30, 2021, just two months after the Rebate Rule was finalized, the court delayed the implementation of the Rule by one year to January 1, 2023.[91]

Following the one-year delay of the Rebate Rule's effective date, insurers and PBMs continued to advocate for further delay or repeal of the rule.[92] At the same time, newly elected President Biden released his framework for a massive infrastructure and economic proposal that would eventually become known as the Build Back Better Act and later pass as the IRA.[93] Commenting on the proposal's prescription drug provisions, President Biden stated that his plan would "help millions of Americans save money and ease their burdens by lowering the cost of prescription drugs."[94]

The Congressional Budget Office ("CBO") estimated that the proposed legislation would increase the total federal deficit by $367 billion over a ten-year period.[95] To pay for the sweeping and costly reforms proposed in the framework, Democrats considered repealing the Rebate Rule, "a move that could save as much as $180 billion in future federal spending . . . to fill

86. *See generally* Pharm. Care Mgmt. Ass'n v. U.S. Dep't of Health & Hum. Servs., No. 21-95, 2021 WL 624229 (D.D.C. Jan. 30, 2021) (postponing the effective date of all provisions within the final rule).

87. Complaint & Prayer for Declaratory and Injunctive Relief at 2, *Pharm. Care Mgmt. Ass'n*, No. 21-95.

88. *Id.* at 77.

89. *Id.* at 89–93.

90. *Id.* at 99–100.

91. *Pharm. Care Mgmt. Ass'n*, 2021 WL 624229, at *1.

92. King, *supra* note 84.

93. *See The Build Back Better Framework: President Biden's Plan to Rebuild the Middle Class*, THE WHITE HOUSE, https://www.whitehouse.gov/build-back-better [https://perma.cc/VZ9K-NR4X].

94. Joseph R. Biden, Jr., President, Remarks by President Biden on How His Build Back Better Agenda Will Lower Prescription Drug Prices (Aug. 12, 2021).

95. CONG. BUDGET OFF., SUMMARY OF COST ESTIMATE FOR H.R. 5376, THE BUILD BACK BETTER ACT (2021), https://www.cbo.gov/publication/57627 [https://perma.cc/8TRF-NRXM].

funding gaps in the multitrillion-dollar legislation."[96] The idea garnered conflicting responses from stakeholders. Many advocates of the plan supported a delay of the rule to pay for President Biden's important infrastructure reform proposals, while others believed that the rule should remain in place to "provide patients meaningful relief at the pharmacy."[97]

After a year of negotiations, Congress passed the IRA, "a slimmed-down version of the Build Back Better bill," in August 2022.[98] The IRA was lauded as a sweeping bill to help meet the needs of the time, including major provisions to reform the U.S. Tax Code, expand climate change policy, and address the cost of health care in America.[99] Importantly, the IRA's healthcare sections included landmark provisions to address the cost of prescription drugs for Medicare members.

The IRA included three main provisions to address rising drug prices. First, the IRA amended the Social Security Act of 1965, allowing Medicare to now negotiate the price of certain high-cost prescription drugs, which will reduce the price that members pay for these drugs.[100] Additionally, the IRA requires drug manufacturers to pay rebates to the government if the prices of the drugs that Medicare covers rise faster in one year than the rate of inflation.[101] Finally, the IRA imposes a $2,000 annual out-of-pocket maximum on drug plans for Medicare members, a significant step to reducing drug costs for seniors who require expensive medications.[102] Commentators expect the changes to provide significant relief for many Medicare members who fall into the drug coverage "donut hole," a coverage gap that leaves Part D beneficiaries responsible for one hundred percent of the cost of drugs once they have met the monetary coverage limit prescribed by Medicare.[103]

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96. Sarah Owermohle & Adam Cancryn, *Democrats Eye Rebate Rule Repeal for Savings*, POLITICO (July 27, 2021, 10:00 AM), https://www.politico.com/newsletters/politico-pulse/2021/07/27/democrats-eye-rebate-rule-repeal-for-savings-796739 [https://perma.cc/T3S4-XT22].

97. Robert King, *Congress to Add Delay to Part D Rebate Rule to Help Pay for Infrastructure Package*, FIERCE HEALTHCARE (July 23, 2021, 1:05 PM), https://www.fiercehealthcare.com/payer/pharma-pushes-back-congress-flirtation-delaying-rebate-rule-to-help-pay-for-infrastructure [https://perma.cc/2FP8-THK5].

98. Kelly Anne Smith, *The Inflation Reduction Act Is Now Law—Here's What It Means for You*, FORBES ADVISOR (Aug. 23, 2022, 8:56 AM), https://www.forbes.com/advisor/personal-finance/inflation-reduction-act [https://perma.cc/BUP8-5GH3].

99. *See id.*

100. Inflation Reduction Act, Pub. L. No. 117-169, § 11001, 136 Stat. 1818, 1833–34 (2022).

101. *Id.* § 11101.

102. *Id.* § 11201.

103. Juliette Cubanski, Tricia Neuman, Meredith Freed & Anthony Damico, *How Will the Prescription Drug Provisions in the Inflation Reduction Act Affect Medicare Beneficiaries?*, KAISER FAM. FOUND. (Jan. 24, 2023), https://www.kff.org/medicare/issue-brief/how-will-the-prescription-drug-provisions-in-the-inflation-reduction-act-affect-medicare-beneficiaries [https://perma.cc/2Q7L-WHEC]; *see also* Joshua Rubin, *The Effects of Medicare's Donut Hole and Congress's Solution*, 20 ANNALS HEALTH L. ADVANCE DIRECTIVE 148, 148–49 (2010) (explaining the effects of the "donut hole" coverage gap).

Although Congress originally intended to fully repeal the Rebate Rule in the IRA,[104] the final legislation merely delayed implementation of the rule to January 1, 2032.[105] The change was necessary to comply with the Byrd Rule for reconciliation bills, which requires that "provisions in a reconciliation bill cannot increase the deficit in any fiscal year."[106] By delaying the Rebate Rule's implementation to 2032, the CBO estimated $122.2 billion in federal savings, which allowed Congress to pay for the expensive drug reform measures included in the IRA.[107] With this delay, implementation of the Rebate Rule remains paused until 2032 unless President Biden or Congress take action to further delay or repeal the rule.

II. IMPLEMENTATION OF THE REBATE RULE WILL CONTRIBUTE TO CONCERNING INCREASES IN PRESCRIPTION DRUG SPENDING

The controversy surrounding the finalization and implementation of the Rebate Rule is rooted in concerns over its economic impact.[108] Due to the role that PBMs play in prescription drug pricing,[109] any regulatory changes to address or limit the scope of PBMs' power necessarily impacts the cost of drugs for both overall Medicare expenditures and individual beneficiaries.[110] This Part examines actuarial studies and financial estimates of the Rebate Rule's impact on federal Medicare spending and out-of-pocket costs for Medicare Part D beneficiaries. First, Section A explores general trends in prescription drug costs and the impact that these trends have on federal spending and Medicare members. Section B then suggests that the Rebate Rule will raise the costs of Part D premiums and prescription drugs for members and increase federal spending on Medicare.

104. *White House Should Repeal Drug Rebate Rule as Part of Inflation Reduction Act Agreement*, COMM. FOR A RESPONSIBLE FED. BUDGET (Aug. 16, 2022), https://www.crfb.org/press-releases/white-house-should-repeal-drug-rebate-rule-part-inflation-reduction-act-agreement [https://perma.cc/Q3NQ-KXE8].

105. Inflation Reduction Act § 11301.

106. *Reconciliation 101*, COMM. FOR A RESPONSIBLE FED. BUDGET (Aug. 13, 2021), https://www.crfb.org/papers/reconciliation-101#byrd [https://perma.cc/Y4SK-MQRP].

107. Juliette Cubanski, Tricia Neuman & Meredith Freed, *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, KAISER FAM. FOUND. (Jan. 24, 2023), https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act [https://perma.cc/U4VE-VZJ3].

108. *See, e.g.*, *White House Should Repeal Drug Rebate Rule as Part of Inflation Reduction Act Agreement*, *supra* note 104.

109. *See supra* Section I.B.

110. *See infra* Section II.A.1.

A. *Evaluating Alarming Trends in Health Care and Prescription Drug Spending*

Federal Medicare spending has increased dramatically throughout the past decade.[111] More worrisome, projections and studies from various government agencies and economists estimate that future Medicare spending will increase at a faster rate than in recent years.[112] To evaluate the rise in health care spending generally, as well as the specific impact that prescription drugs play in these trends, it is important to first understand the funding structure of Medicare Part D. Then, this Section will explore the problems associated with rampant and unsustainable spending increases on prescription drugs.

1. The Link Between Medicare Part D and Federal Spending

Medicare Part D expenditures receive funding from three sources. Part D costs are financed primarily through general revenues authorized by Congress, which contributed to seventy-four percent of Part D funding in 2021.[113] The remaining financing sources for Part D costs include a combination of member premiums, representing fifteen percent of total funding, and state contributions, covering the remaining eleven percent.[114] Because the majority of Part D funding comes from federal revenue rather than member premium contributions, increases in Part D spending can have a large impact on overall federal spending.

Since the introduction of Part D coverage, Medicare health expenditures on prescription drugs have tripled from over $38 billion in 2006 to nearly $120 billion in 2021.[115] Although some of this rapid growth in Part D expenditures can be attributed to large increases in enrollment,[116] "multiple

111. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T OF HEALTH & HUM. SERVS., NATIONAL HEALTH EXPENDITURES BY TYPE OF SERVICE AND SOURCE OF FUNDS, CY 1960-2021, https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nationalhealthaccountshistorical [https://perma.cc/5VXK-FFHF] (showing over $900 billion in Medicare expenditures in 2021, a sixty-five percent increase compared to the nearly $545 billion spent in 2011).

112. *See* Juliette Cubanski & Tricia Neuman, *What to Know About Medicare Spending and Financing*, KAISER FAM. FOUND. (Jan. 19, 2023), https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-spending-and-financing [https://perma.cc/PZ9N-KLN4] ("Between 2020 and 2030, Medicare per capita spending is projected to grow at a faster rate than between 2010 and 2020, on par with average annual growth in per capita private health insurance spending (5.4 [percent] vs. 5.3 [percent]).").

113. *Id.*

114. *Id.*

115. CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T OF HEALTH & HUM. SERVS., *supra* note 111.

116. *See supra* Section I.A.

prescription drug cost and utilization trends . . . have varying effects on underlying costs."[117]

Medicare Part D plans are designed such that the member is responsible for initial prescription drug costs before the drug plan begins to pay for benefits. Once a member reaches their deductible amount, they pay twenty-five percent of prescription drug costs, with the remaining costs covered by their drug plan.[118] If the member reaches the catastrophic coverage period, Medicare begins to cover more of the drug costs.[119] This Part D cost-sharing structure means that Medicare spends more on drug costs for members who utilize drugs at a high rate.

2. Spending on Prescription Drugs Is Increasing at an Unsustainable Rate

Part D expenditures have undergone "an erratic growth pattern" since the program's inception.[120] Part D spending has spiked in recent years due to extreme price increases in specialty drugs[121] and drug prices that have risen faster than inflation.[122] Not only do these rampant increases in drug prices impact federal and Medicare beneficiary spending, they also have grave impacts on the health outcomes of American seniors.

Medicare spending has steadily increased throughout the past decades, and projections indicate these trends will continue.[123] According to CBO projections, Medicare spending will "increase from $630 billion in 2019 to $1.3 trillion in 2029," a two hundred percent overall increase.[124] During that same ten-year time period, CBO further estimates that Medicare spending

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117. 2022 BDS. OF TRS. OF FED. HOSP. INS. & FED. SUPPLEMENTARY MED. INS. TR. FUNDS ANN. REP. 112, https://www.cms.gov/files/document/2022-medicare-trustees-report.pdf [https://perma.cc/XRJ6-G3J3].

118. *Phases of Part D Coverage*, MEDICARE INTERACTIVE, https://www.medicareinteractive.org/get-answers/medicare-prescription-drug-coverage-part-d/medicare-part-d-costs/phases-of-part-d-coverage [https://perma.cc/PX3U-B6MR].

119. *Id.*

120. BDS. OF TRS., *supra* note 117, at 112.

121. *New HHS Reports Illustrate Potential Positive Impact of Inflation Reduction Act on Prescription Drug Prices*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Sept. 30, 2022), https://www.hhs.gov/about/news/2022/09/30/new-hhs-reports-illustrate-potential-positive-impact-inflation-reduction-act-prescription-drug-prices.html [https://perma.cc/MFF6-AA4K] ("Drug spending is heavily driven by a relatively small number of high-cost products. The cost of specialty drugs has continued to grow, totaling $301 billion in 2021, an increase of [forty-three percent] since 2016. Specialty drugs represented [fifty percent] of total drug spending in 2021.").

122. *See* Juliette Cubanski & Tricia Neuman, *Prices Increased Faster than Inflation for Half of All Drugs Covered by Medicare in 2020*, KAISER FAM. FOUND. (Feb. 25, 2022), https://www.kff.org/medicare/issue-brief/prices-increased-faster-than-inflation-for-half-of-all-drugs-covered-by-medicare-in-2020 [https://perma.cc/E3N7-WACX].

123. *See* JULIETTE CUBANSKI, TRICIA NEUMAN & MEREDITH FREED, KAISER FAM. FOUND., THE FACTS ON MEDICARE SPENDING AND FINANCING 3 (2019), https://collections.nlm.nih.gov/master/borndig/101754945/Issue-Brief-Facts-on-Medicaid-Spending-and-Financing.pdf [https://perma.cc/7HZ7-NJSA].

124. *Id.* at 5.

as a share of the total federal budget will increase from 14.3 percent to 18.3 percent.[125]

Perhaps more important than the financial pressure that prescription drugs place on federal spending and beneficiary costs, rising drug prices also impact the overall health and welfare of the Medicare population. Unaffordable drugs lead to a phenomenon known as cost-related medication noncompliance, where a patient delays filling a prescription, does not fill their prescription altogether, or skips or modifies their dose to take a smaller dose than prescribed due to the cost of their medication.[126] Although forgoing important medication may not be desirable for a patient, they often have no choice, as the prohibitive cost of some prescription drugs prevents them from affording "basic necessities."[127]

This practice contributes to a variety of unfavorable health outcomes, including "poor health, hospital admissions, higher healthcare costs and preventable death" in Medicare members.[128] Noncompliance with drug treatments is estimated to lead to "premature deaths of 112,000 beneficiaries a year, making it a leading cause of death in the [United States], ahead of diabetes, influenza, pneumonia, and kidney disease."[129] Additionally, poor medication compliance has been shown to be greater in populations of individuals with low socioeconomic status.[130] As a result, the issue of Part D members being unable to afford their medication further perpetuates existing health disparities among socioeconomic statuses.[131] Moreover, because seniors may develop additional health issues and diagnoses as a result of noncompliance with drug therapy, projections indicate an additional $17.7 billion in annual Medicare spending on avoidable medical costs due to

125. *Id.*

126. *See* Farrah Nekui et al., *Cost-Related Medication Nonadherence and Its Risk Factors Among Medicare Beneficiaries*, 59 MED. CARE 13, 14 (2021).

127. S. Michael Ross, *What Are the Main Reasons for Noncompliance of Medication?*, CUREATR (Mar. 3, 2020), https://blog.cureatr.com/what-are-the-main-reasons-for-noncompliance-of-medication [https://perma.cc/J5KN-GMJT].

128. Press Release, W. Health, New Study Predicts More than 1.1 Million Deaths Among Medicare Recipients Due to the Inability to Afford Their Medications (Nov. 19, 2020), https://www.westhealth.org/press-release/study-predicts-1-million-deaths-due-to-high-cost-prescription-drugs [https://perma.cc/JQ8E-RXF2].

129. *Id.*

130. *See* Nadia Mercado, Kylie Stengel & Tiernan Meyer, *Medication Adherence Disparities Linked to Race, Socioeconomic Factors*, AVALERE (Feb. 28, 2022), https://avalere.com/insights/medication-adherence-disparities-linked-to-race-socioeconomic-factors [https://perma.cc/GM9L-FR5B] ("Avalere's analysis finds that across the disease states analyzed, a smaller proportion of Hispanic and Black beneficiaries had sufficient adherence when compared to White beneficiaries. Additionally, a lower share of beneficiaries in the lowest [socioeconomic status] quartile had sufficient adherence compared to beneficiaries in the highest [socioeconomic status] quartile.").

131. *See generally* Paula A. Braveman, Catherine Cubbin, Susan Egerter, David R. Williams & Elsie Pamuk, *Socioeconomic Disparities in Health in the United States: What the Patterns Tell Us*, 100 AM. J. PUB. HEALTH (2010) (describing socioeconomic health disparities in the United States).

health complications.[132] It is clear when observing these concerning trends that the Medicare program, designed to cover the health care costs and safeguard the financial security of elderly Americans,[133] is not fulfilling its purpose as it exists today.

B. THE REBATE RULE'S IMPACT ON FEDERAL SPENDING AND MEDICARE MEMBERS' OUT-OF-POCKET COSTS

The Rebate Rule, introduced to address rising prescription drug costs, may actually lead to unintended consequences for Medicare Part D beneficiaries and expenditures. As a function of the rulemaking process, HHS solicited comments from stakeholders who would be impacted by the proposed changes of the rule.[134] These reports and studies from various government agencies, activist groups, and pharmacy industry lobbyists indicate concern surrounding the financial impact of the Rebate Rule.

Comments from stakeholders illustrate concern about the rule's purpose and rationale. According to one pharmacy industry association, the reasoning supporting the removal of the safe harbor allowing prescription drug rebates is "at best anecdotal and at worst circular."[135] Critics of the rule have argued that the rule contains conceptual flaws in its construction—that it "does not provide strong evidence supporting its foundational claim that rebates are tied to higher list prices" and that "[it] is not appropriately targeted to meet its stated goals."[136]

Although the rule was intended to address members' out-of-pocket costs by passing valuable rebates to members directly at the pharmacy, this move has the reverse impact on premium amounts for Medicare beneficiaries. Though the rule is estimated to decrease member out-of-pocket costs by $93 billion, Part D premiums are estimated to increase by $50 billion as a result of the rule's changes.[137] Essentially, the Rebate Rule functions to redistribute the costs of prescription drugs, along with the rebate savings, among Part D beneficiaries and the Medicare program. As discussed in Part III, the IRA

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132. *High Drug Prices and Patient Costs: Millions of Lives and Billions of Dollars Lost*, COUNCIL FOR INFORMED DRUG SPENDING ANALYSIS (Nov. 18, 2020), https://www.cidsa.org/publications/xcenda-summary [https://perma.cc/F9FA-E6CF].

133. *See An Overview of Medicare*, KAISER FAM. FOUND. (Feb. 13, 2019), https://www.kff.org/medicare/issue-brief/an-overview-of-medicare [https://perma.cc/RDY2-8ND2].

134. *See, e.g.*, PELZER & SPITALNIC, *supra* note 67, at 1; PHARM. RSCH. & MFRS. OF AM., *supra* note 67, at 3.

135. Jacqueline Renfrow, *PCMA Report Says HHS Rebate Rule Would Significantly Boost Drug, Part D Spending*, FIERCE HEALTHCARE (Apr. 8, 2019, 7:42 AM), https://www.fiercehealthcare.com/payer/pcma-calls-proposed-drug-rebates-rule-poorly-conceived [https://perma.cc/H9G7-T854].

136. ALEX BRILL, CONCERNS REGARDING THE PROPOSED RULE TO RESTRICT DRUG MANUFACTURER REBATES IN MEDICARE PART D AND MEDICAID MCOS 3 (2019), https://www.pcmanet.org/wp-content/uploads/2019/04/MGA-Report-on-Proposed-Rebate-Restriction.pdf [https://perma.cc/ES9X-EEH7] (emphasis omitted).

137. Renfrow, *supra* note 135.

mitigates concerns with members' out-of-pocket costs.[138] Therefore, the impact of the rule on Part D premiums is now the important consideration when evaluating the Rebate Rule's effect on Medicare members directly.

In conducting its analysis of the rule, the Centers for Medicare and Medicaid Services ("CMS") Office of the Assistant Secretary for Planning and Evaluation commissioned studies from two independent actuarial consulting firms, Milliman and Wakely.[139] Milliman's analysis illustrates the financial implications of the rule. In modeling a scenario with "no behavioral changes,"[140] Milliman assumes that rebates paid to PBMs are completely eliminated under the rule.[141] The results demonstrate the distributive effects of the rule. Total cost to Part D members would decrease by $14.5 billion from 2020 to 2029, encompassing a $40.8 billion decrease in member cost-sharing amounts with a $26.4 billion increase in member premiums.[142] In terms of federal spending, however, total government Medicare costs would increase by $34.8 billion.[143] The remaining cost reduction would be felt by drug manufacturers, whose liability through the coverage gap discount program would decrease by $20.6 billion.[144]

The Wakely actuarial study yielded similar results to the Milliman report.[145] Wakely estimated that the average Medicare Part D beneficiary would experience a premium increase of around eight percent as a result of the rule.[146] These beneficiaries would also have their average cost-share

138. *See infra* Section III.A.

139. *See Prescription Drug Pricing: ASPE Resources Related to Safe Harbor Rule*, OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, U.S. DEP'T OF HEALTH & HUM. SERVS. (Jan. 31, 2019), https://aspe.hhs.gov/reports/prescription-drug-pricing-aspe-resources-related-safe-harbor-rule [https://perma.cc/Y7YV-GZXA].

140. Milliman's "No Behavioral Changes" scenario "hold[s] all other assumptions constant," analyzing only the impact of the Rebate Rule without considering PBM or drug plan responses to the rule. JAKE KLAISNER, KATIE HOLCOMB & TROY FILIPEK, MILLIMAN, INC., IMPACT OF POTENTIAL CHANGES TO THE TREATMENT OF MANUFACTURER REBATES 1 (2019), https://aspe.hhs.gov/sites/default/files/private/pdf/260591/MillimanReportImpactPartDRebateReform.pdf [https://perma.cc/26QV-ALM9].

141. *Id.* at 7 ("We analyzed the impact of Part D manufacturer rebates no longer being excluded from the Federal Anti-Kickback Statute.").

142. *Id.* at 1 tbl.1.

143. *Id.*

144. *Id.*

145. *Compare id.* (showing the total financial impact of removing the rebate safe harbor on various stakeholders in the drug delivery system), *with* JULIA LAMBERT, TIM COURTNEY & DREW MCSTANLEY, WAKELY CONSULTING GRP., ESTIMATES OF THE IMPACT ON BENEFICIARIES, CMS, AND DRUG MANUFACTURERS IN CY2020 OF ELIMINATING REBATES FOR REDUCED LIST PRICES AT POINT-OF-SALE FOR THE PART D PROGRAM 4 tbl.1 (2018), https://aspe.hhs.gov/sites/default/files/private/pdf/260591/WakelyImpactAllPartiesManufacturerRebatesPointSale.pdf [https://perma.cc/RG9B-ZJ7A] (showing the per member per month financial impact of replacing PBM rebates with point-of-sale discounts by party).

146. LAMBERT ET AL., *supra* note 145, at 2.

amounts decrease by about 9.5 percent.[147] Although seventy percent of non-low-income beneficiaries would have their out-of-pocket costs rise, the net effect of the financial impacts would yield a two percent decrease in total out-of-pocket costs for beneficiaries.[148] Importantly, Wakely estimated that the point at which a member experienced a net savings in their out-of-pocket costs would "occur at an annual spend of $2,200 to $2,500."[149]

Ultimately, after considering the Milliman and Wakely studies, the CMS Office of the Actuary estimated that the rule would increase total drug spending by $137 billion and lead to federal increases in Medicare Part D spending of $196.1 billion through 2029.[150] After balancing member out-of-pocket savings against increases in member premiums and federal Medicare spending, the Office of the Actuary found that the net effect of the rule would be around $170 billion over ten years.[151]

III. CONSIDERING THE NECESSITY OF THE REBATE RULE

Due to the alarming trends in prescription drug pricing,[152] much attention has been given to reform efforts that address the cost of drugs.[153] In this Part, Section A first explains that the primary goal of the Rebate Rule—to reduce drug costs for seniors—is already met by multiple provisions of the IRA that address the rising cost of prescription drugs for Medicare members. The IRA meets the Rebate Rule's aim of reducing individual members' drug costs by capping out-of-pocket drug spending at $2,000 per beneficiary, suggesting that the costs of the rule—increases in member premiums and federal Medicare spending—do not outweigh the reduction in out-of-pocket costs. Section B then proposes repeal of the Rebate Rule to ensure Part D premiums do not increase for Medicare beneficiaries and to prevent further increases in federal spending on Medicare.

A. THE INFLATION REDUCTION ACT ACCOMPLISHES MANY DRUG PRICING REFORM GOALS

Following through on President Biden's plan to address prescription drug prices, the IRA included several prescription-drug related provisions specifically targeted to reduce out-of-pocket spending for Medicare members.[154]

147. *Id.*

148. *Id.*

149. *Id.*

150. PELZER & SPITALNIC, *supra* note 67, at 1 tbl.1.

151. *Id.* at 2 tbl.2 (showing $170.9 billion net effect on Medicare beneficiaries).

152. *See supra* Section II.A.

153. *See, e.g.*, *The Build Back Better Framework: President Biden's Plan to Rebuild the Middle Class*, *supra* note 93.

154. *See supra* notes 100–03 and accompanying text.

These provisions are expected to dramatically lower healthcare costs for Americans.[155]

The first of the IRA's major drug provisions involves Medicare drug negotiations.[156] Historically, drug plans were unable to negotiate the prices of prescription drugs covered under Medicare due to a "noninterference" clause, which provides that the government "may not interfere with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] sponsors."[157] The IRA amended this provision, now requiring Medicare to negotiate the price of certain high-cost prescription drugs, thus ensuring that list prices for these drugs will remain competitively priced.[158] Under the IRA, brand-name and biologic drugs covered under Part D that are historically high-cost drugs in Medicare are eligible for negotiation.[159] This provision alone is expected to reduce the price of the negotiated drugs by twenty-five to sixty-five percent.[160] The CBO estimates this provision will lead to $98.5 billion in Medicare savings from 2022 to 2031.[161]

The second major drug-related IRA provision requires drug manufacturers to pay rebates to the government if the prices of Medicare-covered drugs rise faster than the rate of inflation in a given year.[162] The CBO estimates this provision will reduce the net federal deficit by $63.2 billion from 2022 to 2031.[163] The revenues generated by rebate payments will contribute to the Medicare Supplementary Medical Insurance trust fund, from which Medicare Part D benefits are paid.[164]

Finally, the IRA caps out-of-pocket prescription drug spending for Medicare Part D members by imposing a $2,000 annual out-of-pocket maximum.[165] Although this provision is estimated to increase federal Medicare spending by $30 billion due to required benefit redesigns to comply with the law, an out-of-pocket maximum provides the most direct relief to Part D members.[166] This provision will decrease total drug costs for the nearly 1.5 million Medicare

155. *The Inflation Reduction Act Lowers Health Care Costs for Millions of Americans*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Oct. 5, 2022), https://www.cms.gov/newsroom/fact-sheets/inflation-reduction-act-lowers-health-care-costs-millions-americans [https://perma.cc/RL2P-9MVZ].

156. Inflation Reduction Act, Pub. L. No. 117-169, § 11001, 136 Stat. 1818, 1833–34 (2022).

157. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2098.

158. Inflation Reduction Act § 11001.

159. Cubanski et al., *supra* note 103.

160. Rachel Murphy, *How Prescription Drug Negotiations Will Impact Medicare Beneficiaries*, INVESTOPEDIA (Sept. 6, 2022), https://www.investopedia.com/perscription-drug-negotiations-medicare-beneficiaries-6503437 [https://perma.cc/CA9P-4ZWM].

161. Cubanski et al., *supra* note 107.

162. Inflation Reduction Act § 11101.

163. Cubanski et al., *supra* note 107.

164. *Id.*

165. Inflation Reduction Act § 11201.

166. Cubanski et al., *supra* note 107.

beneficiaries who spend over $2,000 on prescription drugs each year by reducing their yearly drug spending exposure to $2,000.[167]

B. THE REBATE RULE SHOULD BE REPEALED

The Rebate Rule should be repealed to ensure Part D premiums do not increase for Medicare beneficiaries and to prevent further increases in federal spending on Medicare. Because the IRA sufficiently addresses the rising cost of prescription drugs, the Rebate Rule now serves as a superfluous method to address drug costs. In light of the IRA's major drug reform provisions, the Rebate Rule's disruption to the PBM and drug delivery system is no longer necessary to reform drug pricing and reduce prices for prescription drugs.

Recall the Wakely study that evaluated the impact of the Rebate Rule.[168] A key finding of Wakely's analysis centered around its "estimate that the annual drug spend at which [Medicare] beneficiaries begin to see cost sharing reductions exceed premium increases is between $2,200 and $2,500."[169] Because this group of Medicare beneficiaries will already receive significant relief through the IRA's provision instituting a $2,000 out-of-pocket maximum on Medicare drug plans, ultimately the benefits of the Rebate Rule do not outweigh its costs, namely an increase in Part D premiums and overall federal spending. Therefore, repealing the Rebate Rule will lead to federal budget savings of $400 billion and ensure Part D premiums do not increase for members.[170]

Because the Rebate Rule was promulgated through the rulemaking process by HHS, the rule can be repealed through similar means and congressional action is not required to repeal the rule. Even though congressional support is not needed to accomplish repeal of the rule, there is broad support from lawmakers and stakeholders for President Biden and HHS to undertake this action.[171] Shortly after Congress passed the IRA, a group of lawmakers urged President Biden to permanently repeal the Rebate Rule to "restore the promise of the Inflation Reduction Act."[172] By repealing the Rebate Rule, President Biden can protect long-term budgetary savings and follow through on his promise to ensure prescription drug costs remain affordable for Medicare members.

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167. Cubanski et al., *supra* note 103.

168. *See supra* notes 145–49 and accompanying text.

169. LAMBERT ET AL., *supra* note 145, at 4.

170. *White House Should Repeal Drug Rebate Rule as Part of Inflation Reduction Act Agreement*, *supra* note 104.

171. *See, e.g.*, *id.*

172. Letter from Members of Congress to Joseph R. Biden, President 1 (Sept. 8, 2022), https://golden.house.gov/sites/evo-subsites/golden.house.gov/files/evo-media-document/9.8.22%20POTUS_Rebate%20Rule%20Repeal%20letter.pdf [https://perma.cc/8HCF-65FW].

CONCLUSION

The Rebate Rule is one of many reform efforts introduced in recent years to address rising prescription drug costs. The Rule, which modifies federal antikickback safe harbor protections for PBM rebates and replaces the protection with a new safe harbor for point-of-sale drug discounts for Medicare members, was implemented with good intentions, but ultimately fails to deliver its goal. In light of the IRA's drug pricing reform measures, which achieve many similar objectives as the Rebate Rule, the Rule should be repealed to contain federal Medicare spending. Addressing the rising costs of prescription drugs remains an important objective for policymakers. As the plight of the Rebate Rule illustrates, prescription drug reform efforts must be carefully constructed to ensure that they properly balance the competing interests between ensuring low out-of-pocket costs for individual Medicare members and reigning in federal drug spending.